

The Permanente Medical Group, Inc.

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November 3, 2003

Mark McClellan, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 14-71
Rockville MD 20857
301-827-2410

Dear Dr. McClellan,

We are writing this letter to voice our personal support to have PLAN B emergency contraception switched to over-the-counter (OTC) status. We believe that there is no medical justification for continued prescription status. To the contrary, we believe that this is a compelling medical and social interest in making Plan B even more readily available to women than it already is.

At Kaiser Permanente in Northern California, we are responsible for the care of 664,000 women of reproductive age. Our health plan and medical group is committed to preventive medicine to improve the health of our members and our communities. The prevention of unintended pregnancies is one of our major goals. The widespread availability of emergency contraception is an important tool in pursuit of that goal. We aggressively promote information and access to emergency contraception. We attempt to minimize barriers to the timely access of emergency contraception. In the Northern California region we stock Plan B in our medical offices and make it available to our members on a walk in basis and without any co-payment. In 2002 we prescribed over 15,000 Plan B prescriptions.

The medical evidence demonstrates that Plan B is more effective in averting pregnancy when taken earlier. Making Plan B available OTC should decrease the interval between unprotected intercourse and administration. This would be expected to further boost efficacy.

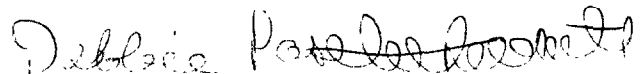
In our experience we have not had safety concerns nor seen unintended health consequences. We believe that Plan B demonstrates a safety profile that is superior to most of the OTC agents of all categories currently available. It has virtually no contraindications. Finally, there is no evidence to support the concern that offering Plan B on an OTC basis would increase risk-taking behavior or diminish regular contraceptive use.

We hope that you will give strong consideration to approving Plan B for over-the-counter status.

Sincerely,



Ruth Shaber, MD
Director, Women's Health Services
Kaiser Permanente, Northern California



Debbie Postlethwaite, RNP, MPH
Women's Health Director of Projects
Kaiser Permanente, Northern California

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